REMARKS

This Amendment is submitted as a full and complete response to the outstanding Office Action dated August 27, 2002. By this Amendment, applicants have cancelled Claims 2, 6, 12, and 15 without prejudice and have amended Claims 1,3-5, 7, and 13. Accordingly, it is now believed that amended independent Claims 1 and 7 and the claims dependent thereon have been placed in condition for allowance.

With respect to Claims 1-16, the Examiner has rejected the same under 35 USC 112 as being indefinite for failing to particularly point out and distinctly claim the subject which applicants regard as their invention. He has stated that Claims 1-6 and 16 recite a method for the formulation and delivery of an acid-labile pharmaceutical but no steps are recited for the delivery of the agent. Further, the Examiner has stated that the phrase "from among at least the group of" does not recite Markush language. His comment that amending the phrase to -- selected from the group consisting of -- would overcome this rejection is thankfully noted. In view of this, applicants have amended Claims 1 and 3-5 so as to overcome each and every one of these rejections. Thus, it is believed that the rejection based upon 35 USC 112 has been overcome.

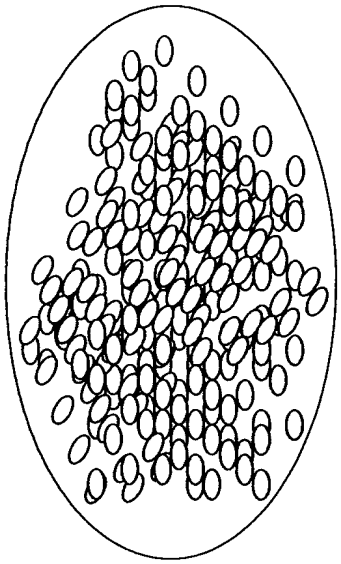
With respect to the action on the merits, it is noted that the Examiner has rejected Claims 1-10 and 12-16 under 35 U.S.C. 102 as being allegedly anticipated by Bengtsson, International Publication No. WO 95/01783. Alternatively, he has rejected Claims 1-10 and 12-16 under 35 U.S.C. 102 as being allegedly anticipated by Oishi et al, Japanese Publication No. 05-194225. Further, the Examiner has rejected Claims 1 through 16 under 35 U.S.C. 103 as being drawn to obvious subject matter in light of Bengtsson. Finally, while he has likewise rejected Claims 1 through 16 under 35 U.S.C. 102 as being allegedly anticipated by Oishi et al, it is believed that he has meant to reject the same under 35 U.S.C. 103 as being unpatentable over Oishi et al. The Examiner has set forth his reasons for this rejection on pages 2-5 of this Official Office Action. However, applicants respectfully disagree with the Examiner in these contentions.

Nevertheless, and in an effort to better define the present invention over the cited prior art, applicant has now amended extensively independent Claims 1 and 7. It is submitted that none of the prior art references can, singly or

in any combination be deemed to anticipate or make obvious all of the new and novel features as now recited with particularity in amended independent Claims 1 and 7.

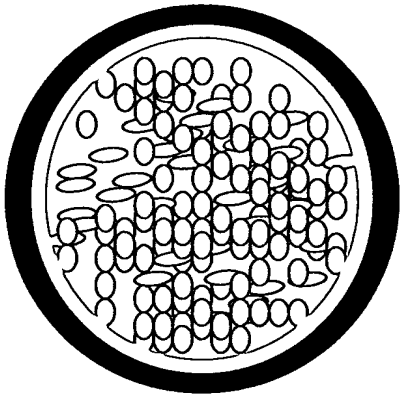
In particular, amended independent Claim 1 has been drafted so as to recite the method for the formulation and delivery of an acid-labile pharmaceutical compound which includes the step of combining the active pharmaceutical compound in the form as one of a tablet, a capsule, and a powder with a basic salt as one of a suspension and a solution having a pH greater than 7.0 so as to convert the acid-labile pharmaceutical compound into a non-enteric coated solid or liquid formulation. Further, there is recited the step of delivering the non-enteric coated liquid formulation by an artificial feeding tube inserted into the patient's gastrointestinal tract. Claim 7 recites an acid-labile pharmaceutical compound that has been drafted similarly to the method of Claim 1.

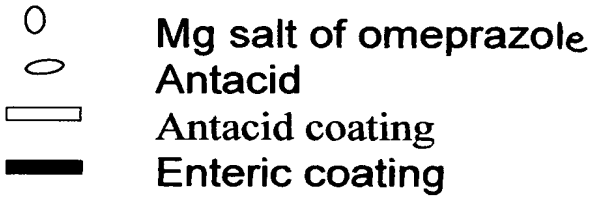
There is illustrated below a graphical representation of the formulation of the present invention:



PPI
Antacid

International Pub. No. WO 95/01783 to Bengtsson et al merely discloses a method of making an oral pharmaceutical formulation and a composition that includes an acid-labile pharmaceutical compound "omeprazole" which is combined with a basic salt of magnesium. The Bengtsson et al. reference teaches that the oral enteric-coated formulation is formed of a core material of an active substance containing a magnesium salt of omeprazole, a subcoating applied to the core material, and an enteric coating layer applied to the subcoating. There is depicted be;ow a graphic representation of the formulation in the Bengtsson et al reference:



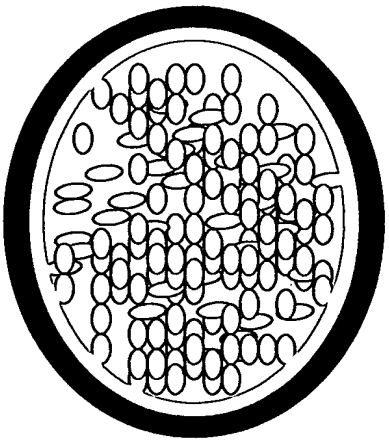


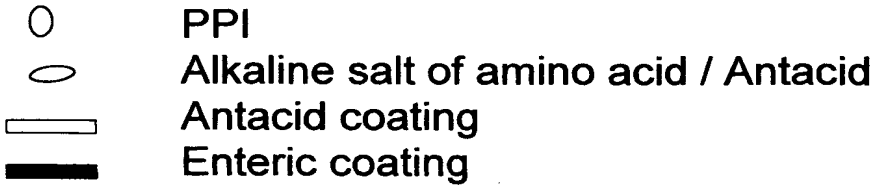
Clearly, the Bengtsson et al reference does not teach or suggest an acid-labile pharmaceutical compound that could be converted to a non-enteric coated liquid formulation. Further, the Bengtsson et al reference does not teach or suggest that the non-enteric coated liquid formulation is delivered to patients by an artificial feeding tube inserted into the gastrointestinal tract.

The enteric-coated formulation of the Bengtsson et al reference will slow down the release of this medication (magnesium salt of omeprazole). On the other hand, the non-enteric coated formulation of the present invention as recited in amended independent Claims 1 and 7 will have a much faster absorption of the substituted benzimidazole than the enteric-coated formulation, thereby resulting a shorter time needed to achieve its peak plasma concentration (blood levels), higher plasma concentrations, and a faster onset of action. As a result, the non-enteric coated formulation of the present invention will produce superior acid suppression during the initial 5-6 hours after administration of the medication. It is submitted that this broad and general teaching of an oral enteric-coated formulation in Bengtsson et al does not, in any way, anticipate or make obvious the present invention as recited with particularity in amended Claims 1 and 7.

The Japanese Pub. No. 05-194225 to Oishi et al merely discloses a stabilized antiulcer agent-containing preparation that contains a mixture of acid-labile pharmaceutical compounds such as omeprazole, lansoprazole, and rabeprazole and of buffers such as calcium carbonate, aluminum hydroxide, and magnesium hydroxide so as to maintain a weakly alkaline pH in the range of 8-9.

There is shown below a graphical representation of the formulation in the Oishi et al reference:





However, this Oishi et al reference is likewise deficient in its teaching of an acid-labile pharmaceutical compound which is converted into a non-enteric coated liquid formulation for delivery by an artificial feeding tube inserted into the patient's gastrointestinal tract as recited in amended Claims 1 and 7 of the present invention. Therefore, it is believed that amended independent Claims 1 and 7 of the present invention are clearly distinguishable over the prior art of record and are thus in condition for allowance.

The enteric-coated formulation of the Oishi et al reference will also slow down the release of this medication (pharmaceutical compounds). On the other hand, the non-enteric coated formulation of the present invention as recited in amended independent Claims 1 and 7 will have a much faster absorption of the substituted benzimidazole than the enteric-coated formulation, thereby resulting a shorter time needed to achieve its peak plasma concentration (blood levels), higher plasma concentrations, and a faster onset of action. As a result, the non-enteric coated formulation of the present invention will produce superior acid suppression during the initial 5-6 hours after administration of the medication. It is submitted that this broad and general teaching of an oral enteric-coated formulation in Oishi et al does not, in any

way, anticipate or make obvious the present invention as recited with particularity in amended Claims 1 and 7.

Moreover, it is likewise submitted that since Claims 3-5 and 16 and Claims 8-11, and 13-14 are dependent upon respective amended Claims 1 and 7 these claims should be allowable for this reason alone.

In view of the foregoing amendments advanced to the claims, it is now believed that amended independent Claim 1 and 7 and the remaining claims dependent thereon have been placed in condition for allowance. Please refer to the Appendix entitled "Version With Brackets For Deleted Matter And/Or Underlining For Added Matter" showing how the previous version of the specification and/or claims have been modified so as to produce the above clean version submitted in this Amendment. Therefore, a formal Notice of Allowance is believed to be in order and the same is earnestly solicited.

In the event the Examiner is of the opinion that the prosecution of this application may be expedited by direct

contact with applicants' attorney, he is requested to call Davis Chin at (708)403-9688, Orland Hills, Illinois.

Respectfully submitted,

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DC/d
00B-2027
Attachment

APPENDIX

VERSION WITH BRACKETS FOR DELETED MATTER AND/OR UNDERLINING FOR ADDED MATTER

Claims, with corrections shown:

1.(Amended) A method for the formulation and delivery of an acid-labile pharmaceutical compound **selected** from [among at least] the group **consisting** of substituted benzimidazoles and pancreatic enzyme supplements, said method comprising:

a. providing an active pharmaceutical compound;

b. providing a basic salt as one of **a powder,** a suspension and a solution **having a pH greater than 7**;

c. combining said **active** pharmaceutical compound in a form as one of a tablet, a capsule, **and** a powder[, a] **with said basic salt as one of the powder, the** solution and [a] **the** suspension to [provide] **convert** said acid-labile pharmaceutical compound **into a non-enteric coated tablet, capsule or liquid formulation** [.]**;and**

d. delivering the non-enteric coated liquid formulation of said acid-labile pharmaceutical compound to patients who are unable to swallow intact capsules or tablets orally by an artificial feeding tube inserted in the patients' gastrointestinal tract.

3.(Amended) A method for the formulation and delivery of an acid-labile pharmaceutical compound [from among at least the group of substituted benzimidazoles and pancreatic enzyme supplements] as claimed in Claim [2] **1**, wherein said basic salt is one of a Type IA and Type II metal salt.

4.(Amended) A method for the formulation and delivery of an acid-labile pharmaceutical compound [from among at least the group of substituted benzimidazoles and pancreatic enzyme supplements] as claimed in Claim 3, wherein said metal salt is one of sodium, potassium, magnesium, calcium and aluminum [salt].

5.(Amended) A method for the formulation and delivery of an acid-labile pharmaceutical compound [from among at least the group of substituted benzimidazoles and pancreatic enzyme supplements] as claimed in Claim 1, wherein said compound in

said formulation includes a therapeutic dose of said **active** pharmaceutical compound.

7. (Amended) An acid-labile pharmaceutical compound having at least substituted benzimidazoles and pancreatic enzyme supplements, said acid-labile pharmaceutical compound comprising:

a. an active pharmaceutical compound;

b. a basic salt, which basic salt is at least one of **a powder,** a solution and **a** suspension;

c. said one of **said powder,** said solution and **said** suspension having a pH greater than 7.0;

d. said active pharmaceutical compound and said basic salt combined as at least one of a form of a tablet, capsule, and powder; [and]

e. said at least one of a form of a tablet, capsule and powder provided to

said one of [a] **said** solution and **said** suspension to [provide] **convert** said acid-labile pharmaceutical compound **into a non-enteric coated tablet, capsule, or liquid formulation which is** operable to provide at least one of neutralization of gastric acid and temporary stimulation of gastric acid secretion[.]**; and**

the non-enteric coated liquid formulation of said acid-labile pharmaceutical compound being delivered to patients who are unable to swallow intact capsules or tablets orally by an artificial feeding tube inserted in the patients' gastrointestinal tract.

13. (Amended) An acid-labile pharmaceutical compound as claimed in Claim 7, wherein [said compound may be administered into a gastrointestinal tract by at least one of orally and by artificial tube,] said **artificial feeding** tube [being] **is** at least one of nasogastric tube, nasoduodenal tube, [hasojejunal] **nasojejunal** tube, [oragastric] **orogastric** tube, [oraduodenal] **oroduodenal** tube [orajejunal] **,orojejunal** tube, [gastrotomy] **gastrostomy** tube and jejunostomy tube.